

Memorandum

To: Board Members

Date: October 14, 2003

From: Communication And Public Education Committee

Subject: Committee Activities – October Update

The Communication and Public Education Committee met October 9, 2003, in the Sheraton Gateway Hotel – LAX. Minutes of this meeting are provided in this tab section as Attachment A.

Also provided at the end of this tab section is the committee's quarterly update report to the board on the committee's strategic objectives.

Action Items:

1. Emergency Contraception Fact Sheet

RECOMMENDATION 1: Approve a new fact sheet that under California law must be provided to patients receiving emergency contraception directly from pharmacists, reflecting a lower reading level in phrasing, and changes in dosing and in the time to initiate treatment.

Note: after the October 9 meeting of the Communication and Public Education Committee where this recommendation was made, the board was notified that two key agencies that prepared this fact sheet did not officially approve it. The following information and documents in Attachment 1 describe this situation.

Background:

In 2002, legislation took effect that allows pharmacists to provide emergency

contraception to patients if they complete specific education, have a protocol with a physician and provide patient counseling. The law also requires the board to provide a fact sheet for the public on emergency contraception that includes (1) indications for use, (2) the appropriate method for using the drug, (3) the need for medical followup, and (4) other appropriate information. The board is required to develop this fact sheet in consultation with the California Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association and other health care organizations. (See California Business and Professions Code section 4052(b)(3) in Attachment 1.)

Since January 2002 to meet this mandate, the board has made available an Emergency Contraception Fact Sheet produced by Pharmacy Access Partnership in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacists Association and the California Department of Health Services. This fact sheet, titled "Key Facts About Emergency Contraception" is provided in Attachment 1. The board has printed this fact sheet in its newsletter and has it available for downloading from the Web site.

This fact sheet states that EC is effective if taken within 72 hours of unprotected sex. Recent research indicates that EC may be effective if initiated within five days. Additionally a popular form of EC is now provided in one dose, where as the fact sheet describes two doses. According to Pharmacy Access Partnership, more than 700 pharmacists in California operate under protocols with physicians with different timing and dosing information that now reflect community standards.

As such the proponents of EC have suggested that the fact sheet needs revision. Additionally some proponents have suggested a fact sheet using a 6th-7th grade reading level instead of the current 10th grade level.

A new draft of the fact sheet has been provided to the board for approval, which is required by the law. Additionally SB 490 (Alpert, Chapter 651) and SB 545 (Speier, Chapter 652) both bills made modifications to the requirements for pharmacists providing EC. A copy of relevant excerpts of these laws is provided in Attachment 1, although these changes do not directly affect the content of the fact sheet.

The problem: currently the American College of Obstetricians and Gynecologists and the California Medical Association do not agree with a change to the five-day period to initiate treatment and dosing changes from that reported on the current fact sheet until the topic is reviewed during 2004. This dissent was not known to

the committee at the time it made the recommendation to proceed with a new fact sheet on October 9.

As such the board may wish to delay to approving the new fact sheet until all the proponents agree with the changes. Alternatively, the board could approve the fact sheet with the changes suggested by the Pharmacy Access Partnership, or some combination of changes as suggested in the attached materials.

2. Web Site Redesign

RECOMMENDATION 2: Sponsor a Web Page Design Contest among pharmacy students to redesign the board's Web Page. The winner would be acknowledged in a future board newsletter

Background: the board's budget for educational materials is very limited. The board has established partnerships with CPhA and CSHP to assist in the printing and mailing of board materials. Additionally, the board intends to use its Web site as an ever-increasing avenue for communication with licensees and the public.

The board's Web page needs to be redesigned. The current Web page (see Attachment 2) was created by a staff person in 1998, and now is dated. An additional point of information is that the Governor's Office several years ago directed that all state agencies need to redesign their Web pages so they resemble the Governor's Web site (also included in Attachment 1). The board lacked the staff expertise to do this redesign, so this project is overdue.

During a brainstorming session at the last meeting, the Communication and Public Education Committee suggested that the board sponsor a contest among pharmacy school students to create a new Web page design. The winner could be featured in a future board newsletter, and perhaps on the Web site itself.

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Items of Interest:

Significant Activities

3. Update on *The Script*

The October 2003 *The Script* was recently printed and mailed to California pharmacies. The CPhA's Education Foundation is mailing the issue to all California pharmacists by special funding provided by AstraZenega. The board is grateful for this collaboration and assistance.

The next issue of *The Script* is being developed and should be mailed in January 2004, and will focus on new laws.

4. Update on *Health Notes*

The committee plans to revise "Pain Management" (originally published in 1996) to update the issue regarding new drug therapies for pain and the legislative changes that will eliminate the triplicate prescription requirements. The committee is seeking partnerships with the private sector to reduce the costs of producing this issue. This issue should be ready by March 2004.

5. Consumer Brochure on Buying Drugs from Other Countries

The board has produced information on purchasing prescription drugs for lower costs. The information has been printed in a format of two brochures:

- Purchasing drugs from foreign countries and why this can be dangerous
- Ways consumers can reduce their expenses for prescription drugs and discount programs for prescription drugs available to the public

The goal is to provide patients with information so that they may make informed decisions about where they obtain their prescription drugs. The brochures have been distributed at public events since this summer.

6. Public Outreach and Education Activities

The board has shown its interest and enthusiasm for attendance at consumer information forums and fairs to provide our publications and information about the board. Since the last board meeting, the board has maintained an active public outreach program with existing staff assisting in the process.

The board has also developed a continuing education course in a PowerPoint format to present to pharmacists and others about the board, including enforcement issues, legislative issues and questions and answers about pharmacy law. This is a two-hour program provided by board members and board staff.

Recent outreach activities since the last board meeting are listed in the committee's status report, and include:

- July 2003 – Board President Jones and staff present continuing education program for 60 pharmacists at the Santa Barbara Pharmacists Association about the Board of Pharmacy
- August 2003—Board staffs booth at Sacramento's Consumer Health Fair, sponsored by Kaiser, AARP, Area 4 Agency on Aging and Congressman Matsui
- September 2003 -- Board President Jones attends the Districts 7 & 8 Meeting of the National Association of Board of Pharmacy
Also: staff presents information to 40 pharmacists at the Long-Term Care Academy meeting
- October 2003 -- Board staffs an information booth at CSHP's Seminar 2003 in Sacramento
Also:
Board staffs an information booth at Los Angeles County Health Fair and Senior Festival (more than 2,000 people attended)
And:
Board staffs an information booth at Sacramento's Healthy Aging Summit where 3,000 people attended.

5. Development of Public Outreach Plan with the Department of Consumer Affairs

Board staff began working with the Department of Consumer Affairs on public education and outreach, implementing Sunset Review recommendations of the Joint Legislative Sunset Review Committee and Department of Consumer Affairs. The department encouraged this partnership as a means to develop additional public education materials.

An action plan has been developed by the department to develop printed materials and media events. The board reviewed this plan at the July Board Meeting. The committee will activate this plan in the future.

Attachment 1

Emergency Contraception Fact Sheets and Law



KEY FACTS ABOUT

Emergency Contraception

Emergency Contraception is a safe and effective way to prevent pregnancy after sex.

Consider using emergency contraception if:

- You didn't use a contraceptive during sex, or
- You think your contraceptive didn't work.

What are Emergency Contraceptive Pills?

Emergency contraceptive pills contain the same medication as regular birth control pills and help to prevent pregnancy.

There are three basic types of emergency contraceptive pills:

- Plan B™ progestin-only pills
- Preven™ estrogen/progestin pills
- High doses of regular oral contraceptive pills.

Pills should be started within 72 hours (three days) after unprotected sex.

Emergency contraceptive pills require two doses:

- First dose within 72 hours of unprotected intercourse
- Second dose 12 hours after the first dose

Emergency contraceptive pills are more effective the sooner they are taken.

Safe and effective.

- Progestin-only pills reduce the risk of pregnancy by 89%.*
- Combined estrogen/progestin pills reduce the risk of pregnancy by 75%.*
- For regular, long-term use, other contraceptive methods are more effective.
- Emergency contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

* Pregnancy risk reduction based on one-time use.

Won't cause an abortion.

- Emergency contraceptive pills are NOT the same as RU-486 (the abortion pill).
- Emergency contraceptive pills are not effective after implantation; they cannot interrupt an established pregnancy.

Won't harm a developing fetus.

- If emergency contraceptive pills are mistakenly taken during pregnancy, they will not harm the developing fetus.
- Using emergency contraceptive pills will not affect a woman's ability to become pregnant in the future.

Women can keep pills at home in case of emergency.

- Many women find it convenient to have emergency contraceptive pills on hand in case of an emergency.
- Medical providers or your pharmacist can provide emergency contraceptive pills before they are needed.

Medical follow up after taking Emergency Contraceptive Pills.

- If you don't get a normal period within 3 weeks, you can use an at home pregnancy test to find out if you are pregnant. You may also visit your healthcare provider to check to see if you are pregnant.
- It is important to visit your doctor or clinic if you need a regular birth control method or services to prevent sexually transmitted infections or AIDS.

In California all income-eligible women and men may receive no-cost family planning services through the Family PACT program. If you don't have a doctor or clinic, call **1-800-942-1054** to find a Family PACT provider near you.

*Prepared by the
Pharmacy Access
Partnership in
consultation with the
American College of
Obstetricians and
Gynecologists District
IX, the California
Pharmacists Association
and the California State
Department of Health
Services. Part of this
material adapted from
PATH. Reviewed by the
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Key Facts About Emergency Contraception

Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception if:

- You didn't use a contraceptive during sex, or
- You think your contraceptive didn't work.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills contain the same medication as regular birth control pills, and help to prevent pregnancy. There are three basic types of Emergency Contraceptive pills:

- Plan B TM progestin-only pills
- Preven TM estrogen/progestin pills
- High doses of regular oral contraceptive pills.

Don't wait! Take EC as soon as possible.

- It is best to take EC within 24 hours of having unprotected sex.
- EC may work up to five days after sex, but it is more effective if it is taken earlier. Don't delay!
- EC may require one or two doses, depending on the product. Talk to your pharmacist or doctor.

EC is safe and effective.

- Progestin-only pills reduce the risk of pregnancy by 89 percent.*
- Combined estrogen/progestin pills reduce the risk of pregnancy by 75 percent.*
- For regular, long-term use, other contraceptive methods are more effective than EC.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

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EC won't cause an abortion.

- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill).
- Emergency Contraceptive pills are not effective after pregnancy has occurred and cannot interrupt it.

EC won't harm a developing fetus.

- If Emergency Contraceptive pills are taken mistakenly during pregnancy, they will not harm the developing fetus.
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Medical follow-up after taking Emergency Contraceptive pills

- If you don't get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic if you need a regular birth control method or information about preventing sexually transmitted infections, such as HIV/AIDS.

In California all women and men with eligible incomes may receive free family planning services through the Family PACT program.

**If you don't have a doctor or clinic,
call 1-800-942-1054 to find a
Family PACT provider near you.**

Revised October 2003

<Revised Text>


emergency
contraception



PHARMACY
access
partnership

*A Center
of the Public
Health Institute*

RECEIVED BY CALIF.
BOARD OF PHARMACY
2003 OCT 10 PM 3:01

October 8, 2003

Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Dear Patricia,

As John Jones and Paul Riches can verify, the August 14, 2003 meeting of the Pharmacy Access Partnership generated lively discussion regarding Emergency Contraception timing and dosing (see enclosed minutes for this portion of the meeting). We brought this issue to the larger group to address the state mandated (per SB1169) EC Fact Sheet and the inconsistency it presents with current pharmacy practices in California. Currently more than 700 pharmacists in California operate under protocols with different timing and dosing information.

Based on group input we revised the EC Fact Sheet (see attached) to reflect new information on timing and dosing, and adjust it to a more appropriate – lower - reading level.

However, Tracey St. Julien with ACOG and Robin Flagg Strimling with CMA informed us this week that their organizations are not comfortable with the proposed timing and dosing information. Below is a summary of the ACOG and CMA positions.

In reviewing the proposed Fact Sheet, we ask the Board to review the three issues (timing, dosing and general word changes) separately. There is no opposition to the "general" word changes. There may be a way to accommodate EC pharmacists without offending ACOG and CMA on the dosing issue.

Input from ACOG and CMA

The ACOG Committee on Practice Bulletins - Gynecology reported that the committee opted not to revise the practice bulletin on emergency contraception at this time. The EC dosing and timing issue is scheduled to be reviewed, and possibly revised, in 2004. Therefore, District IX cannot currently endorse the revised EC timing and dosing information Fact Sheet.

CMA's support for timing and dosing changes in the EC Fact Sheet is contingent upon ACOG's support. Because ACOG has decided to stick with its original 2004 review schedule, and not make any revisions until that time, CMA has decided to also refrain from endorsing the proposed timing and dosing changes.

1. General Wording

The proposed EC Fact Sheet has been modified to read at a 6-7th grade level. Currently it is at a 10th grade level. Thus, much of the current information is lost to EC consumers. No member of the Pharmacy Access Partnership has opposed these general changes in the proposed new wording.

2. Dosing

More than 700 EC protocols are currently in use in California that permit pharmacists to provide a single 1.5mg dose or double dose (0.75mg each) of Plan B (see attached Exhibit B from current protocol). Because many pharmacists are now opting for a single Plan B dose, the current EC Fact Sheet is confusing to women who receive the product at a pharmacy.

We ask the Board to consider one of two options:

(a) Adopt some variation of proposed wording for dosing:

"EC may require one or two doses, depending on the product. Talk to your pharmacist or doctor." *Alternatively:* "Talk to your pharmacist or doctor about dosing information."
OR

(b) Eliminate any reference to dosing information on the EC Fact Sheet.

3. Timing

Many medical organizations have endorsed a treatment interval of 120 hours, including Planned Parenthood of America (see "Recent Information on EC Treatment Interval"). ACOG has sent out a news release on this issue (see attached). The current pharmacy practice in California is to initiate therapy up to five days. The proposed new wording addresses this reality.

However, if the Board wishes to consider alternative wording to that proposed, we offer the following:

"Don't Wait! Take EC as soon as possible.

- Use EC within three days of unprotected sex
- The sooner you take EC the more effective it is"

If I may offer any assistance to the Board when addressing the revised EC Fact Sheet please do not hesitate to contact me.

Sincerely,



Jane Boggess, PhD
Director

Enclosures

Minutes August 14, 2003 Pharmacy Access Partnership
New EC Fact Sheet
California EC Protocol – Exhibit B
Recent Information on EC Treatment Interval
ACOG News Release

Action Items – EC Fact Sheet (per SB1169)

The Public Health Institute and the California Pharmacists Association request changes to the Fact Sheet that pharmacists give EC patients

1. General wording (all text except specific information about “dosing” and “timing”)

Problem: The current reading level is 10th grade level – making it difficult for some women to understand

Change: Text has been revised to a lower reading level – content is the same

2. Dosing information

Problem: Current pharmacists' protocols in California allow one dose of Plan B, but Fact Sheet only presents information about 2 doses

Change: Revise text as per one of the options below

Option 1: “EC may require one or two doses, depending on the product. Talk to your pharmacist or doctor.”*

Option 2: “Talk to your pharmacist or doctor for dosing information.”

Option 3: *Eliminate any reference to dosing on the Fact Sheet*

3. Timing information

Problem: Current pharmacists' protocols in California allow initiation of EC up to five days. Fact Sheet instructs use only up to 3 days

Change: Revise text as per one of the options below

Option 1: “It is best to use EC within 24 hours of having unprotected sex. EC may work up to five days after sex, but it is less effective than if taken earlier”*

Option 2: “Use EC within three days of unprotected sex”

* Text is identical to original information distributed as a result of August 14, 2003 Pharmacy Access Partnership meeting - not endorsed by CMA or ACOG.

Pharmacy Access Partnership
Minutes - August 14, 2003
East Bay Community Foundation – Dalziel Building
Oakland California

LIST OF ATTENDEES:

Martha Baird	Mary Gatter	E. Bilma Schwarz
Heidi Bauer	Nicole Gray	Linda Simkin
Christi Black	Jan Johanson	Marjorie Singer
Pat Blackburn	John Jones	Shannon Smith-Crowley
Jane Boggess	Peter Koo	Tracey St. Julien
Sharon Cohen	Katie McCall	Robin Strimling
Sheena Cresswell	Mackenzie Melton	Kathy Toner
Phil Darney	Nicole Monastersky	Debbie Wilkerson
Kathryn Duke	Mike Negrete	George Wolfe
Jackie Gardener	Paul Riches	
Paul Lofholm	Hector Sanchez-Flores	

EC Fact Sheet: New Timing and Dosing Information

New EC information* shows that (1) EC may prevent pregnancy up to five days after unprotected sex, although it is more effective if taken earlier and (2) Progestin-only (Plan B) may be taken in either one dose of 1.5 mg levonorgestrel or two doses (.75 mg each) 12 hours apart. Approximately 700 protocols in CA are now in use that permit treatment up to five days and allow a one (.75 mg) or two (1.5 mg) dosing of Plan B. There is a need to bring the Fact Sheet into line with current information and practices.

Pat Blackburn facilitated a discussion around updating the timing and dosing information presented on the CA State Mandated Fact Sheet (viewed at www.PharmacyAccess.org or http://www.pharmacy.ca.gov/pdfs/emergency_contraception.pdf). She broke the discussion down by issue: dosing and timing.

Dosing:

- Main Question: should the Fact Sheet contain information on dosing, or does the pharmacist inform the patient?
- Mary Gatter recommended the language “EC requires one or two doses depending on which product you take (ask the pharmacist)...”
- Nancy Shanfeld recommended eliminating the line “EC pills are more effective the sooner they are taken”.
 - Wolfe agreed with Shanfeld's idea.
- Mike Negrete expressed concern that women receiving the Fact Sheet would potentially be sharing it with friends / family and that there should be mention of information on dosing.
- Paul Lofholm voted for no information on dosing on the Fact Sheet.
- Phil Darney felt that some advice on how to use EC would be important.
 - Heidi Bauer agreed with Phil Darney, that dosing information gives women the message that it's a short term of treatment.

* Recent WHO data (Lancet 2002; 360:1830-1880) for levonorgestrel collected from a large (n=2758) randomized trial conducted in 10 developed and developing countries showed that it prevented a high proportion of pregnancies if taken within five days of unprotected intercourse. Rodrigues et al (AM J Obstet Gynecol 2001;184:531-537) reported similar findings for the Yuzpe regimen. Both studies, however, suggest lower efficacy with longer delay between treatment and unprotected intercourse. Two studies conducted by Ellertson et al (AM J Obstet Gynecol 2003; 101(6):1160-1167 and AM J Obstet Gynecol 2003; 101(6):1160-1167) additionally suggest that there may be wider variations in the effective drug dosages, and a longer window of time to take the contraceptive, than previously believed.

- Based on group discussion, Pat Blackburn asked the group to move forward on the following recommendations:
 - Add "talk to your pharmacist or doctor".
 - Leave specific communication about dosing between the pharmacists.
 - Be vague – do not specify when second dose is taken on the fact sheet.

Timing:

- Peter Koo felt that we should keep the information presented as simple as possible.
- John Jones said that if we include information on taking EC at 5 days people will wait until the 5th day to take it.
- Hector Sanchez-Flores stated that teens are concrete thinkers; if three days is used they will understand the sense of urgency and will want to avoid an unintended consequence. However if the longer goal is to have EC before an accident happens, the details of the wording around urgency would be secondary for the young person.
- E. Bilma Schwarz said that maybe we were misrepresenting teens – we don't want folks to miss the bus on this issue. Five days is important to convey. Ignorance is a larger issue rather than laziness. E. Bilma Schwarz noted EC is most effective is taken within 24 hours.
- Martha Baird felt we should stress the need to take EC right away.
- Phil Darney felt that if we listed taking EC between 3-5 days people would interpret taking it at the 4th day so instead to say the sooner the better.
- Shannon Smith-Crowley suggested using the current terminology "within 3 days".
- Phil Darney wondered why ACOG & CMA representatives were not accepting the new information around timing as there were three studies out there supporting this new information, and he was part of a press conference team for ACOG that released the news.
- Kathy Toner suggested stating "Don't wait!! EC should be taken the sooner the better".
- CMA and ACOG stated that they were NOT okay with language that states "up to 5 days".
 - ACOG & CMA wanted to focus on three days but were willing to compromise with the addition of "may work up to 5 days after sex".
- Wolfe added that in the spirit of SB 1169 the views of ACOG and CMA were important and stressed the need to compromise.

The following organizations and individuals were able to reach consensus on the draft wording.

- Robin Strimling, CMA*
- Shannon Smith Crowley and Tracey St Julian, ACOG*
- Mary Gatter, Planned Parenthood
- Phil Darney, UCSF
- Paul Riches and John Jones, State Board of Pharmacy
- Representatives from CPhA, Longs, CA STD Control Branch, Harbor-UCLA, etc...
- Individual advisors to the Pharmacy Access Partnership

Some draft wording for the Fact Sheet:

- Don't Wait: Emergency Contraception should be taken as soon as possible.
- EC is more effective the sooner it is taken after unprotected sex.
- EC may work up to 5 days after sex but it is less effective than if taken earlier.
- EC pills may require either 1 or 2 doses depending on the product chosen (talk to your pharmacist or doctor).

*Pending committee approval

Other suggestions for the Fact Sheet:

- Testing Fact Sheet for literacy level and bringing it down to 6th/7th grade reading level.
 - *Note: this may alter the wording.*
- Making Family PACT information more prominent in last section of the Fact Sheet.

- Adding a revision date on the Sheet to distinguish between versions.
- Re-designing the look and feel of the Fact Sheet.

Next steps:

- Pat Blackburn to email new language to Partnership advisors.
- Partnership to get reading level assessment test done and send back to larger group for comment.
- Direct comments to Pat Blackburn.
- Pat Blackburn will deliver suggestions to the Board of Pharmacy the week of September 2nd.
- Tracey St. Julien and Robin Strimling will take back new paragraph to ACOG and CMA committees' for review.

Emergency Contraception Drug Therapy Collaborative Agreement Protocol

Brands and Doses of Dedicated Products and Oral Contraceptive Pills Used For Emergency Contraception

Brand	Manufacturer	Dose	Ethinyl Estradiol per Dose (mcg)	Levonorgestrel per Dose (mg)*
One Dose Regimen *				
<i>Dedicated Emergency Contraception</i>				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
<i>Oral Contraceptive Pills</i>				
Levora	Watson	4 white tablets per dose	120	0.60
Levlen	Berlex	4 light-orange tablets per dose	120	0.60
Lo/Ovral	Wyeth-Ayerst	4 white tablets per dose	120	0.60**
Low-Ogestrel	Watson	4 white tablets per dose	120	0.60**
Nordette	Wyeth-Ayerst	4 light-orange tablets per dose	120	0.60
Alesse	Wyeth-Ayerst	5 pink tablets per dose	100	0.50
Aviane	Duramed	5 orange tablets per dose	100	0.50
Levlite	Berlex	5 pink tablets per dose	100	0.50
Ogestrel	Watson	2 white tablets per dose	100	0.50**
Ovral	Wyeth-Ayerst	2 white tablets per dose	100	0.50**
Tri-Levlen	Berlex	4 yellow tablets per dose	120	0.50
Triphasil	Wyeth-Ayerst	4 yellow tablets per dose	120	0.50
Trivora	Watson	4 pink tablets per dose	120	0.50

"Two Dose Regimens" is adapted from RA Hatcher, *et al*, *Contraceptive Technology: Seventeenth Revised Edition*. New York NY: Ardent Media, 1998. Updated by Felicia Stewart, MD, 2001.

* Recent WHO data (*Lancet* 2002; **360:1830-1880**) for levonorgestrel showed that a 1.5mg single dose can substitute two 0.75mg doses 12h apart. This simplifies the use of levonorgestrel without an increase in side effects. Pregnancy rates were slightly lower for the single dose regimen, but not statistically significant. Similar findings on single dose efficacy were obtained by Arowojulu *et al* (*Contraception* 2002; **66:269-273**).

** The progestin in Ovral, Lo/Ovral, Low-Ogestrel, Ogestrel and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

Recent Information on EC Treatment Interval
August 12, 2003

Source	Public Information
New Mexico Pharmacists Association http://www.nm-pharmacy.com/ec_key_facts.htm http://www.nm-pharmacy.com/ec_consent.htm	<p>"Pills should be started within 120 hours (five days) after unprotected sex."</p> <p>"EC treatment should be started within 5 days (120 hours) of unprotected sex."</p>
Planned Parenthood http://www.plannedparenthood.org/library/BIRTHCONTROL/EmergContra.htm	<p>"ECPs ... can reduce the risk of pregnancy if started within 120 hours after unprotected vaginal intercourse. They work best when the first dose is taken within 72 hours - during this time they can reduce the risk of pregnancy by 75-89 percent. The sooner they are started, the better. "</p> <p>"Studies have shown ECPs reduce the risk of pregnancy when started within 120 hours of unprotected intercourse, but the sooner the dosing begins, the more effective the treatment " "Because ECPs have a five-day window of effectiveness and require multiple doses of pills, the popular term "morning- after pill" is misleading."</p>
California Family Health Council EC Bus Ad Campaign <i>Spring / Summer 2003</i>	<p>"When things don't go as planned...you have 3-5 DAYS after sex to prevent a pregnancy with EMERGENCY CONTRACEPTION (EC) pills."</p>
NOT-2-LATE http://ec.princeton.edu/questions/ectime.html	<p>"However, several recent studies have found that the pills are effective when the first dose is started up to 5 days (120 hours) after unprotected intercourse."</p> <p>"A recent large study by the World Health Organization found that effectiveness declined significantly with increasing delay between unprotected intercourse and the initiation of treatment. This finding suggests that ECPs should be taken as soon after unprotected intercourse as is practical."</p>
Physicians for Reproductive Choice and Health Emergency Contraception: A Practitioner's Guide	<p>"Clinicians have begun offering ECPs up to 120 hours after unprotected intercourse based on recent studies. However, ECPs are most effective when taken in the first 12 hours..."</p>
Choice USA http://www.choiceusa.org/facts/ec_5.pdf	<p>"New research shows emergency contraception may still be effective up to 120 hours (5 days) after unprotected sex. However, research also shows that emergency contraception may be more effective the sooner it is taken. Therefore, the sooner you take it, the better."</p>

Recent Information on EC Treatment Interval
August 12, 2003

Source	Public Information
Reproductive Health Technologies Project http://www.rhtp.org/ec/ec_faqs.htm	<p>"Actually, labels for the FDA approved products say EC should be used within 72 hours of unprotected intercourse and recent research shows this window can be extended to 120 hours, or 5 days. However, there is no reason to delay treatment; the sooner, the better."</p>
Back Up Your Birth Control Campaign http://www.backupyourbirthcontrol.org/toolkits/print/ec-factsheet.htm	<p>"Now, new research shows emergency contraception is still effective when that "time window" is extended up to 120 hours (or 5 days)."</p>
Planned Parenthood NYC EC Billboard Campaign <i>Spring / Summer 2003</i>	<p>"EC can prevent pregnancy up to 5 days after unprotected sex. But don't wait – the sooner the better."</p>
The Access Project http://www.theaccessproject.org/	<p>"The sooner EC is taken after an episode of unprotected sex, the better it works. It works up to 5 days after unprotected sex. The 2 doses are taken 12 hours apart (or for Plan B, both pills together)."</p>
Planned Parenthood – Teen Wire http://www.teenwire.org/index.asp <i>Updated May 30, 2003</i>	<p>"It's called emergency contraception (<u>EC</u> for short) and it's easy to get. EC pills reduce the risk of pregnancy if started within 120 hours of unprotected <u>vaginal intercourse</u>, but are most effective if started within 72 hours."</p>
Association of Reproductive Health Professionals ARHP manages the emergency contraception (EC) hotline (1-888-NOT-2-LATE) and website (www.NOT-2-LATE.com). http://www.arhp.org/healthcareproviders/visitingfacultyprograms/ectt/ecnews.cfm	<p>Excerpt from ACOG News Release May 31, 2003: "One observational study found that the 72-hour cutoff for taking EC after unprotected intercourse might be unnecessarily restrictive, since researchers found that differences in success rates for women taking EC within either 72 hours or 120 hours of intercourse were not statistically significant."</p>
ACOG http://www.acog.org/from_home/publications/press_releases/nr05-31-03-5.cfm May 31, 2003	<p>"One observational study found that the 72-hour cutoff for taking EC after unprotected intercourse might be unnecessarily restrictive, since researchers found that differences in success rates for women taking EC within either 72 hours or 120 hours of intercourse were not statistically significant."</p>

ACOG NEWS RELEASE

For Release: May 31, 2003

**Emergency Contraception: Works Up to 120 Hours and in Different Combinations**

WASHINGTON, DC -- Two studies on emergency oral contraception (EC) in the June issue of *Obstetrics & Gynecology* ([Modifying the Yuzpe Regimen of Emergency Contraception: A Multicenter Randomized Controlled Trial](#), [Extending the Time Limit for Starting the Yuzpe Regimen of Emergency Contraception to 120 Hours](#)) suggest that there may be wider variations in the effective drug dosages, and a longer window of time to take the contraceptive, than previously believed.

One observational study found that the 72-hour cutoff for taking EC after unprotected intercourse might be unnecessarily restrictive, since researchers found that differences in success rates for women taking EC within either 72 hours or 120 hours of intercourse were not statistically significant. A large, multi-center randomized trial found that oral contraceptives containing the more common norethindrone-ethinyl estradiol combinations worked approximately as well for EC as the standard levonorgestrel-ethinyl combination used in the traditional "Yuzpe" method of EC, named after early EC researcher Albert Yuzpe.

Study authors note that wider variation in the regimens and timing of EC could benefit women who are unable to obtain EC within 72 hours or who live in areas where it is difficult to obtain the standard Yuzpe combination of hormones. They note that it's not surprising that greater variations in EC regimens are possible. The well-known Yuzpe formulation did not result from systematic drug development or a rigorous evidence base: rather, Yuzpe conducted his EC research using a hormone combination he was already using for other research, and he selected the 72-hour cutoff based on other regimens in Europe he was trying to improve.

Contact for both studies: Charlotte Ellertson, MPA, PhD, Ibis Reproductive Health, Cambridge, MA, at cellertson@ibisreproductivehealth.org.

#

Studies published in Obstetrics & Gynecology, the peer-reviewed scientific journal of The American College of Obstetricians and Gynecologists (ACOG), do not necessarily reflect the policies or opinions of ACOG. ACOG is the national medical organization representing over 45,000 members who provide health care for women.

Current Law:

- 4052(a)(8) Initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice. Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation.
- 4052(b)(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

Enacted by SB 545 and SB 490 and will take effect 1/1/04:

- 4052 (a) (8) (A) Furnish emergency contraception drug therapy in accordance with either of the following:**
- (i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.**
 - (ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.**
- (B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program**

on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(b)(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

Attachment 2

Web Sites of Board and the Administration



CALIFORNIA THE GOLDEN STATE



CALIFORNIA HOMEPAGE HOM



Board of Pharmacy

*Serving the people
of California
since 1891*

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Welcome to the California Board of Pharmacy!

Although prescription drugs can save lives, they can also be dangerous if taken improperly. For that reason, the California State Board of Pharmacy was established in 1891 to protect consumers by licensing and regulating those responsible for dispensing medications to the public.

HOT TOPICS

**Additional Pharmacist
Licensure Exam Sample
Questions Available**

From the days when pharmacists often functioned as "doctor/pharmacist" and frequently filled orders for drugs scribbled on torn pieces of paper, then ground and blended the drugs with a mortar and pestle, pharmacy has evolved into a high-tech, computerized dispensing practice.

Today, all aspects of the practice of pharmacy are regulated by the Board: the practitioner (the pharmacist), the practice site (the pharmacy), and the product (prescription drugs and devices). Even drug manufacturers and wholesalers are regulated.

Please send your
comments

regarding this web site to:
rxwebmaster@dca.ca.gov

Presently, there are more than 76,000 individuals and firms licensed through 12 complex and varied regulatory programs.

The Board's primary mission is to promote and protect the public's health and safety and ensure that consultation and information is provided to patients and other health care providers about drug therapy. The Board also ensures that drugs are dispensed and used correctly and requires that pharmaceutical therapy is provided by highly educated and trained pharmacists who meet the professional standards set by the Board. Further, the Board enforces both state and federal pharmacy statutes requiring competent, efficient, and ethical pharmacy practice.

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"A large part of California's future is going to be in the rapidly growing life science industry, which is not only an engine for economic growth, but holds the key to alleviating vast suffering and improving the health and well-being of literally every person in the world. This is why life sciences is going to be a key focus of our overall economic growth strategy." - Governor Gray Davis

[Los Angeles](#)



Lasting Values, New Direction

Welcome to the Governor's Home Page, part of the new State portal - [my.ca.gov](#) / your online link to California. California is a place where intellect, invention, and imagination come together. As Governor, I am committed to using the technologies of the Internet, many developed in our State, to open the doors of government.

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Flex Your Power

- [See energy saving tips and information on how California is meeting the energy challenge.](#)
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Spotlight on California Statewide Student Tests

- [2003 STAR Test Results](#) **NEW**
- [Academic Performance Index](#)

What's New in California

- [2003 Governor's Environmental and Economic Leadership Award winners selected; to be formally announced November 2003](#) **NEW**
- [Governor's Conference for Women](#)
- [Pre-registration for Do Not Call](#)
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- [Governor's Book Fund](#)
- [First-in-the-nation legislation signed by Gov. Gray Davis](#)
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**Region Life
Sciences Strategic
Action Plan**

**Bay Area Life
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NEW

September 12, 2003 California Snapshot Photo Contest Winners



3rd Place, 17 and Under - "Ocean View and Cliffs"

You are invited to take part in the next California Snapshot photo contest celebrating California's rich cultural and geographic

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What's New



GetGrants!

Interested in learning about Grant opportunities in California? There may be funding opportunities for you! With California's new GetGrants! website, you now have a single, easy-to-use directory that will help you find state grants with just a click of the mouse.

▶ [more...](#)



California Courts Self-Help Center Launches Spanish-language Site

The California Courts' Online Self-Help Center now makes it possible for Spanish-speaking Californians to find a variety of important legal information through Centro de Ayuda de las Cortes de California. The new website is the most comprehensive Spanish-language resource about California courts, providing quick access to information on court procedures, forms, referrals to legal services, and other assistance.

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My First Job

In most cases, success does not happen overnight. It takes hard work and determination. See how these Californians--

How Do I...?



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diversity. **The entry deadline is March 12, 2004.**

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SHOAH

from celebrities to your next door neighbor-- got their careers started.

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Holocaust Era Insurance Claims Deadline is Extended to December 31, 2003

If you are a Holocaust survivor, or the heir of a survivor, you may have a legitimate unpaid Holocaust era life, education, or dowry insurance claim.

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Do you know?

Where do I turn if I have questions about my natural gas or electric utility bill or problems with my utilities?

Click below to find out

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Attachment A

Meeting Minutes of October 9, 2003



California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814

Phone (916) 445-5014

Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GRAY DAVIS, GOVERNOR

Communication and Public Education Committee

Meeting Minutes: October 9, 2003

Sheraton Gateway Hotel – Los Angeles Airport
6101 West Century Boulevard
Los Angeles, CA 90045

Present: Ken Schell, Board Member
James Acevedo, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer

2:20 -- 4:20 p.m.

Call to Order

Acting Co-Chairs Ken Schell and James Acevedo called the meeting to order at 2:20 p.m.

Discussion of Planned Activities to Fulfill Strategic Goals

Ms. Herold led the committee in a review of the publications produced by the board. She explained that the board's education efforts are focused in two areas: (1) to educate the public so that they are more knowledgeable about the prescription medications they take, obtain better therapeutic outcomes and know the board's role as a regulator in California over those who dispense, ship and store prescription drugs, and (2) to educate board licensees and applicants so that they are knowledgeable about laws and board policies, and hence provide higher quality care and services to the public.

Ms. Herold stated that the board's strategic plan identifies public information and licensee education as two key strategic objectives of the board. However, budget constraints imposed on all state agencies over the last few years have hit this program area very hard. The board lost the two positions dedicated to public and licensee outreach because they were vacant and could not be filled. Whereas the board will seek reestablishment of these positions when the budget conditions improve, the current directions from the Department of Finance are that any staffing proposals will not be approved at this time.

The board has also had to redirect money from its printing budget to cover other program areas (e.g., legal services from the Office of the Attorney General). Printing is one of the few discretionary items in the board's budget of \$7.5 million that can be redirected to other areas and is not tied to a specific appropriation (for example as are personnel expenses, rent expenses or pro rata charges).

The committee had been provided with the board's telephone survey of consumers conducted in 2000 regarding consumer awareness of the board, satisfaction with health care in general and specifically with pharmacists and pharmacies. Among the findings were that 75 percent of those surveyed did not know that the board exists, but most of these individuals believe that the regulation of pharmacies is useful, if not necessary, to protecting the public.

The committee discussed at length options for developing or distributing consumer education materials. Some of the proposals were to partner with outside agencies to distribute materials or key board information, perhaps by enclosing flyers or short statements/messages in mailings of utility company or insurance company bills.

Another alternative is to expand the promotion of the board's Web site as one way to provide access to consumer information. Ms. Herold stated that one of the board's priorities for the year is to redesign the board's Web site. The committee discussed various ways to educate the public about the board's Web site as an information source on topical pharmaceutical information. One suggestion was to create small stickers or signs that contain the board's Web site that could be placed on pharmacies' counters or the back of cash registers. Another is to create a contest for pharmacy students – encouraging them to redesign the board's Web site.

Motion: James Acevedo, seconded by Ken Schell: Recommend to the board that it sponsor a Web design contest among pharmacy students for assistance in redesigning the board's Web site.

2-0

The committee also was provided with the joint public outreach plan developed by the Department of Consumer Affairs for working the board.

The committee was provided with the first quarterly status report of the board's strategic goals for 2003/04.

- Status of *The Script*

Ms. Herold stated the October 2003 issue of *The Script* was mailed to all California pharmacies this week. Additionally CPhA's Education Foundation will mail this issue to all California pharmacists, through funding provided by AstraZenega.

The next issue will focus on new pharmacy laws and should be available sometime after January 1, 2004.

- *Health Notes* Publication Plans for the Future

Ms. Herold stated that the board plans on revising *Health Notes*, "Pain Management" (published in 1998) to update the issue regarding new drug therapies for pain and legislative changes that will eliminate the triplicate prescription requirements and establish new requirements for dispensing controlled substances. The committee will seek partnerships with the private sector to reduce the costs of producing this issue.

- Emergency Contraception Fact Sheet

Ms. Herold stated that the board has been asked to approve an updated form of the emergency contraception fact sheet to reflect new treatment guidelines. At the current time, the revisions have not yet been submitted to the board, but will be sent before the October board meeting.

Prescription Drugs from Canada – Brochure on Purchasing Drugs for Lower Costs

Ms. Herold stated that the board's newest brochure on obtaining lower cost prescription drugs has been produced in house and is available and is being distributed at public education events.

Public Outreach Activities

The board strives to provide information to licensees and the public. To this end, it has a number of consumer materials to distribute at consumer fairs and strives to attend as many of these events as possible, where attendance will be large and staff are available to work in the booth.

The board also has developed a PowerPoint presentation on the board containing key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, which usually are well-received by the individuals present. The board also staffs an information booth at the two major pharmacist associations' annual meetings, where a number of licensees can meet with staff one-on-one.

Recent board participation in public and licensee outreach activities.

- July 2003 – Board President Jones and staff present continuing education program for 60 pharmacists at the Santa Barbara Pharmacists Association about the Board of Pharmacy

- August 2003—Board staffs booth at Sacramento's Consumer Health Fair, sponsored by Kaiser, AARP, Area 4 Agency on Aging and Congressman Matsui
- September 2003 -- Board President Jones attends the Districts 7 & 8 Meeting of the National Association of Board of Pharmacy
- Staff presents information to 40 pharmacists at the Long-Term Care Academy meeting
- October 2003 -- Board staffs an information booth at CSHP's Seminar 2003 in Sacramento
- Board staffs an information booth at Los Angeles County Health Fair and Senior Festival (approximately 4,000 people are expected)
- Board staffs an information booth at Sacramento's Healthy Aging Summit

Adjournment

There being no additional business, the meeting was adjourned at 4:15 p.m.

Strategic Plan Status Report
First Quarter 2003-04
Communication and Public Education Committee

Goal: 4: Provide relevant information to consumers and licensees. Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1:	Develop 10 communication venues to the public by June 30, 2005.
Measure:	Number of communication venues developed to the public
Tasks:	<ol style="list-style-type: none"> 1. Convert <i>Health Notes</i> articles into consumer columns or fact sheets for wide-dissemination to the public. 2. Develop and update public education materials. <i>August 2003: Board finalizes purchasing drugs from Canada brochure and revises discount drugs available to Medicare beneficiaries.</i> <i>October 2003: Emergency Contraception fact sheet has suggested revisions to reflect new treatment guidelines.</i> <i>Four brochures targeted for translation into Spanish (Emergency Contraception, Purchasing Drugs for Less, Purchasing drugs from foreign countries and discount drug prices available to Medicare Beneficiaries)</i> 3. Maintain a vigorous, informative Web site. <i>July 2003: Materials for public meetings, including board meetings and most committee meetings placed on Web site for downloading by the public.</i> <i>August 2003: New staff person assigned to revamp Web site, who completes Web site development training</i> <i>September 2003: Board completes pilot testing for integration of enforcement information into license verification portion of Web site. The board will add this look-up feature before January 1, 2004.</i> <i>October 2003: SB 361 enacted which will authorizes verification of licensure when info is downloaded from the board's Web site.</i> 4. Sponsor "Hot Topics" seminars to the public. <i>July 2003: This series, sponsored by UCSF, the Department of Consumer Affairs and the board, concluded in May 2003. All parties are interested in resuming this project if staff are available to coordinate.</i> <i>The first of consumer fact sheets developed from this series is drafted for board review by the Department of Consumer Affairs.</i>

Objective 4.2:	Develop 10 communication venues to licensees by June 30, 2005.
Measure:	Number of communication venues developed to licensees

Tasks:	<ol style="list-style-type: none"> 1. Publish <i>The Script</i> two times annually. <i>October 2003: The Script is published and mailed to all pharmacies. CPhA's Education Foundation will print and mail the newsletter to all California pharmacists.</i> 2. Publish one <i>Health Notes</i> annually. <i>September 2003: Discussions begin to coordinate a major revision to "Pain Management" Health Notes, updating treatment information as well as new requirements for prescribing and dispensing controlled drugs in California enacted by SB 151, which will take effect in a series of stages throughout 2004.</i> 3. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California. <i>July 2003: Board presents PowerPoint continuing education program to 35 MediCal staff in Los Angeles and 60 pharmacists in Santa Barbara.</i> 4. Maintain important and timely licensee information on Web site.
Objective 4.3:	Participate in 20 forums, conferences and public education events by June 30, 2005.
Measure:	Number of forums participated
Tasks:	<ol style="list-style-type: none"> 1. Participate in forums, conferences and educational fairs. <i>August 2003: Board staffs an information booth at Sacramento's Consumer Health Fair, co-hosted by Kaiser, AARP, Area 4 Agency on Aging and Congressman Matsui.</i> <i>September 2003: Board President Jones attends NABP's District VII and VIII annual meeting. Board Member Jones attends the Indian Pharmacist Association Meeting</i> <i>Staff present information to 40 pharmacists attending a Long-Term Care Academy meeting</i> <i>October 2003: Board staffs an information booth at CSHP Seminar 2003</i> <i>Board staffs an information booth at Los Angeles County Health Fair and Senior Festival, over 2,000 people will attend.</i> <i>Board staffs an information booth at Sacramento's Healthy Aging Summit</i>
Objective 4.4:	Respond to 100 percent of information requests from governmental agencies regarding board programs and activities.
Measure:	Percentage response to information requests from governmental agencies
Tasks:	<ol style="list-style-type: none"> 1. By June 1, 2004, submit report to Legislature on statutory requirements for remedial education after four failed attempts on the California pharmacist exam. 2. Provide information to legislators regarding board implementation of statutory requirements. 3. Provide agency statistical data information to the department.

	<p><i>Sept. 2003: Board submits data to department as required.</i></p> <p>4. Board provides information to department on the Bilingual Services Program Survey due September 15, 2003.</p>
Objective 4.5	Respond to 100 percent of public information requests regarding board programs and activities.
Measure:	Percentage response to information requests from the public
Tasks:	<p>1. Respond to public information requests.</p> <p><i>July – Oct. 2003: the board received to 340 public inquiries and four subpoenas. Nearly 80 percent of the public inquiries were responded to within 10 days, and all four of the subpoenas were responded within required timeframes..</i></p>